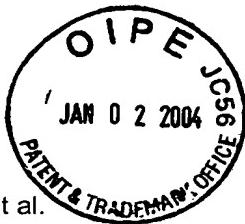


COMMISSIONER FOR PATENTS  
P.O. Box 1450, Alexandria, VA 22313-1450



Docket No.: 300.1003CON  
Date: December 30, 2003

In re application of: Chih-Ming CHEN, et al.  
Serial No.: 10/603,254  
Filed: June 25, 2003  
For: HMG-COA REDUCTASE INHIBITOR EXTENDED RELEASE FORMULATION

Sir:

Transmitted herewith is an **Information Disclosure Statement** in the above-identified application.

- [ ] Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
- [ ] Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
- No fee for additional claims is required.
- [ ] A filing fee for additional claims calculated as shown below, is required:

(Col. 1)	(Col. 2)		SMALL ENTITY		LARGE ENTITY			
	FOR:	REMAINING	HIGHEST	RATE	FEES	OR	RATE	FEES
	AFTER	PREVIOUSLY	PRESENT					
	AMENDMENT	PAID FOR	EXTRA					
TOTAL CLAIMS	* Minus**	=	0	x \$ 9	\$		x \$ 18	\$
INDEP. CLAIMS	* Minus***	=	0	x \$ 42	\$		x \$ 84	\$
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ \$140	\$		+ \$280	\$
				TOTAL: \$		OR	TOTAL: \$	

- \* If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.
- \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
- \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

- Also transmitted herewith are:
  - [ ] Petition for extension under 37 C.F.R. 1.136 (in duplicate)
  - Other: **Form PTO-1449 form**
- [ ] Check(s) in the amount of **\$0.00** is/are attached to cover:
  - [ ] Filing fee for additional claims under 37 C.F.R. 1.16
  - [ ] Petition fee for extension under 37 C.F.R. 1.136
  - [ ] Other:
- The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.
  - Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
  - Any patent application processing fees under 37 C.F.R. 1.17.
  - Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with sufficient postage to the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on December 30, 2003.

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY:

Robert J. Paradiso, Reg. No. 41,240  
DAVIDSON, DAVIDSON & KAPPEL, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
Tel: (212) 736-1940  
Fax: (212) 736-2427



300.1003CON

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner: To Be Assigned                          Art Unit: 1614  
Re: Application of:                                Chih-Ming CHEN, et al.  
Serial No.:                                        10/603,254  
Filed:    June 25, 2003  
For:    **HMG-COA REDUCTASE INHIBITOR  
EXTENDED RELEASE  
FORMULATION**

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

December 30, 2003

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. § 1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

Pursuant to 37 C.F.R. § 1.98(d), copies of the references listed on the accompanying Form PTO-1449 (4 pages) are of record in the parent application (U.S. Patent Application No. 09/435,576) and are not enclosed. If it is determined that any of the listed references are not of record in the parent application, the Examiner is requested to contact the undersigned so that a copy can be forwarded.

This Information Disclosure Statement and accompanying Form PTO-1449 are being filed under C.F.R. § 1.97(b)(3) before the mailing of a first Office Action. Accordingly, no fee is due. In the event any fee is due or overpayment made in connection with the filing of this

300.1003CON

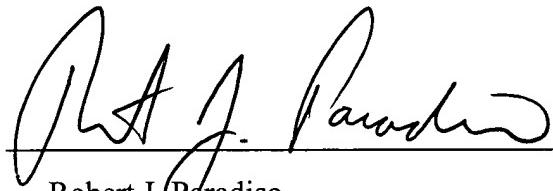
Information Disclosure Statement, the Assistant Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.

It is respectfully requested that the references cited on the accompanying Form PTO-1449 be considered and made of record.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By:



Robert J. Paradiso  
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14th Floor  
New York, New York 10018  
(212) 736-1940



FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE							ATTY. DOCKET NO. 300.1003CON		SERIAL NO. 10/603,254			
<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)											APPLICANTS Chih-Ming CHEN, et al.			
											FILING DATE June 25, 2003		GROUP 1614	
<b>U.S. PATENT DOCUMENTS</b>														
EXAMINER INITIAL								DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE		
	AA	5	8	3	7	3	7	9	11/17/98	Chen et al.	424	465		
	AB	5	8	3	4	0	2	3	11/10/98	Chen	424	497		
	AC	5	8	3	0	5	0	3	11/3/98	Chen	424	480		
	AD	5	7	3	6	1	5	9	4/7/98	Chen et al.	424	480		
	AE	5	7	2	8	4	0	2	3/17/98	Chen et al.	424	481		
	AF	5	6	5	4	0	0	5	8/5/97	Chen et al.	424	480		
	AG	5	6	1	6	5	9	3	4/1/97	Patel et al.	514	321		
	AH	5	5	8	2	8	3	8	12/10/96	Rork et al.	424	472		
	AI	5	5	6	7	4	4	1	10/22/96	Chen	424	494		
	AJ	5	5	5	8	8	7	9	9/24/96	Chen et al.	424	480		
	AK	5	5	4	3	1	5	4	8/6/96	Rork et al.	424	473		
<b>FOREIGN PATENT DOCUMENTS</b>														
								DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION		
												YES	NO	
	AL	9	8	1	1	8	7	9	3/26/98	WO	A61K	9/22		
	AM	9	6	1	9	2	0	1	6/27/96	WO	A61K	9/24		
<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	AN	Hatano, Harumi, et al., Pharmaceutical Preparation Inform of Coated Capsule Releasable at Lower Part Digestive Tract, <i>Caplus</i> , 1997:195672.												
	AO	Cheng, Haiyung, et al., Evaluation of Sustained/Controlled-Release dosage Forms of 3-Hydroxy-3-Methylglutaryl-Coenzyme A (HMG-CoA) Reductase Inhibitors in Dogs and Humans, <i>Pharmaceutical Research</i> (1993), 10:1683-1687.												
	AP	McClelland, Gregory A., et al., Placement of 3-Hydroxy-3-Methylglutaryl-Coenzyme A (HMG-CoA) Reductase Inhibitor Efficacy Through Administration of a Controlled Porosity Osmotic Pump Dosage Form, <i>Pharmaceutical Research</i> (1991), 8:873-876.												
	AQ	Illingworth, D. Roger, et al., Comparative Efficacy of Once Versus Twice Daily Mevinolin in the Therapy of Familial Hypercholesterolemia, <i>Clinical Pharmacology Therapy</i> (1986), 40:338-343.												
EXAMINER									DATE CONSIDERED					
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														



FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE								ATTY. DOCKET NO. 300.1003CON	SERIAL NO. 10/603,254			
<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)									APPLICANTS Chih-Ming CHEN, et al.				
									FILING DATE June 25, 2003				
									GROUP 1614				
U.S. PATENT DOCUMENTS													
EXAMINER INITIAL								DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE	
	BA	5	5	3	2	2	7	5	7/2/96	Grumet	514	567	
	BB	5	5	1	8	7	3	0	5/21/96	Fuisz	424	426	
	BC	5	5	0	8	0	4	0	4/16/96	Chen	424	451	
	BD	5	4	7	2	7	1	2	12/5/95	Oshlack et al.	424	480	
	BE	5	4	7	2	7	0	8	12/5/95	Chen	424	451	
	BF	5	4	5	8	8	8	8	10/17/95	Chen	424	464	
	BG	5	4	5	8	8	8	7	10/17/95	Chen et al.	424	464	
	BH	5	4	1	9	9	1	7	5/30/95	Chen et al.	429	469	
	BI	5	3	6	6	7	3	8	11/22/94	Rork et al.	424	473	
	BJ	5	3	5	6	4	6	7	10/18/94	Oshlack et al.	106	153	
	BK	5	3	5	0	5	8	4	9/27/94	McClelland et al.	424	501	
	BL	5	3	2	4	3	5	1	1/28/94	Oshlack et al.	106	153	
	BM	5	3	0	0	2	8	8	4/5/94	Albright	424	78.08	
	BN	5	2	8	6	4	9	3	2/15/94	Oshlack et al.	424	468	
	BO	5	2	7	3	7	6	0	12/28/93	Oshlack et al.	424	480	
	BP	5	2	4	4	9	1	6	9/14/93	Bokoch	514	460	
	BQ	4	9	7	6	9	6	7	12/11/90	McClelland et al.	424	473	
	BR	4	9	4	6	6	8	6	8/7/90	McClelland et al.	424	473	
FOREIGN PATENT DOCUMENTS													
								DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
												YES	NO
	BS												
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)													
	BT												
EXAMINER								DATE CONSIDERED					
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													



FORM PTO-1449 (REV. 7-80)      U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE <b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)								ATTY. DOCKET NO. 300.1003CON		SERIAL NO. 10/603,254		
								APPLICANTS Chih-Ming CHEN, et al.				
								FILING DATE June 25, 2003		GROUP 1614		
<b>U.S. PATENT DOCUMENTS</b>												
EXAMINER INITIAL								DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
CA	4	9	1	5	9	5	4	4/10/90	Ayer et al.	424	473	
CB	4	8	1	4	1	8	3	3/21/89	Zentner	424	485	
CC	4	6	1	5	6	9	8	10/7/86	Guittard et al.	604	892	
CD	4	5	0	3	0	3	0	3/5/85	Edgren et al.	424	15	
CE	4	4	4	4	7	8	4	4/24/84	Hoffman et al.	424	279	
CF	4	3	4	6	2	2	7	8/24/82	Terahara et al.	560	119	
CG	4	2	3	1	9	3	8	11/4/80	Monaghan et al.	260	343.5	
CH	4	0	8	8	8	6	4	5/9/78	Theeuwes et al.	219	121 LM	
CI	4	0	6	3	0	6	4	12/13/77	Saunders et al.	219	121 L	
CJ	3	9	1	6	8	9	9	11/4/75	Theeuwes et al.	424	424	
CK	3	8	4	5	7	7	0	11/5/74	Theeuwes et al.	128	260	
CL	3	6	7	1	5	2	3	6/20/72	Westphal et al.	260	248 AS	
CM												
CN												
CO												
CP												
CQ												
CR												
<b>FOREIGN PATENT DOCUMENTS</b>												
							DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
											YES	NO
CS												
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)												
	CT											
EXAMINER								DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.												



FORM PTO-1449 (REV. 7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE									ATTY. DOCKET NO. 300.1003CON	SERIAL NO. 10/603,254		
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)									APPLICANTS Chih-Ming CHEN, et al.			
									FILING DATE June 25, 2003	GROUP 1614		
U.S. PATENT DOCUMENTS												
EXAMINER INITIAL								DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
DA	6	0	0	1	3	9	1	12/14/99	Zeidler et al.	424	467	
DB	5	9	8	0	9	4	1	11/6/66	Raiden et al.	424	464	
DC	5	8	9	7	9	1	0	4/27/99	Rosenberg et al.	427	2.14	
DD	5	8	7	4	5	2	2	2/23/99	Figuly et al.	528	422	
DE	5	2	1	1	9	5	1	5/18/93	Sparer et al.	424	426	
DF	5	1	2	0	5	4	8	6/9/92	McClelland et al.	424	473	
DG	4	9	9	7	6	5	8	3/5/91	Alberts et al.	424	473	
DH	4	9	9	4	2	7	3	2/19/91	Zentner et al.	424	422	
DI	5	9	1	6	5	9	5	6/29/99	Chen et al.	424	480	
DJ	6	4	3	6	4	4	1	8/20/02	Sako et al.	424	488	
DK												
DL												
DM												
DN												
DO												
)	DP											
	DQ											
	DR											
FOREIGN PATENT DOCUMENTS												
								DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
												YES
	DS											NO
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)												
	DT											
EXAMINER								DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.												